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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,423	10/02/2003	Gerry Clarke	P1476 US (2650/149)	8445

7590 04/17/2006

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EXAMINER
SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/677,423	CLARKE, GERRY
Examiner	**Art Unit**
Kathleen Sonnett	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2003*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.
  4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-35* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *02 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
  Paper No(s)/Mail Date *10/2/03, 9/1/05*.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 22-24, 26, 29, and 33** are rejected under 35 U.S.C. 102(b) as being anticipated by Solano et al. (U.S. 4,921,478). Solano et al. discloses a catheter including an elongated inner member (22, 38) and a flexible longitudinally oriented outer member (24, 28) that is operably attached to the distal portion of the inner membrane. When a stent is coupled to a distal portion of the flexible outer sheath of the catheter and the delivery device is positioned proximate a target site, the elongated inner member is retracted and the flexible outer member folds adjacent an inner side of the stent to cause the stent to be deployed (Fig. 2, 5A-5C, and col. 5 lines 54-68). Depending on the placement of the stent, it will expand from a distal to a proximal end.

3. Regarding **claims 23-24**, Solano et al. discloses a dilation balloon 84 at the end of the inner member. When inflated, this cap has a diameter greater than the diameter of the stent when the stent is disposed on the flexible outer member and has not yet been expanded by the outer member (see Fig. 9C, 9D). Sometime between the steps depicted in Fig. 9C and 9D, the occluding balloon (77) is totally expanded and the outer member has not yet folded over, causing expansion of a stent placed on it.

4. Regarding **claim 29**, see col. 5, lines 5-7.

5. Regarding **claim 33**, the flexible outer member is considered a sheath since it covers inner member (22, 38).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. **Claim 1, 2, 5, 6, 8, 12-21, 34 and 35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al. (U.S. 5,571,086) in view of Foster (U.S. 6,500,182). Kaplan et al. discloses a catheter system including a flexible outer member (302) and an elongated inner member (320) and a stent being disposed on the outer member of the catheter. When the flexible outer member folds adjacent an inner side as seen in Fig. 3C, the stent is deployed. The end sections of the expandable portion (304) of the outer member (302) form an inverted fold since they are no longer parallel with inner member (320). Kaplan et al. discloses a cap portion as seen in Fig. 3A-C at the distal end of the expandable portion (304). Examiner is considering the portion beyond the expandable region (304) to be the cap portion.

8. Regarding claim 5, positioning of the stent along the catheter system will determine how it is deployed.

9. Regarding claim 8, see col. 8 lines 11-18.

10. Regarding claims 15-17, Kaplan et al. discloses that it is old and well known in the art to including a drug-eluting matrix with a stent delivery system (col. 2 lines 30-67 and claims 1, 2). Kaplan et al. discloses that the drug is a therapeutic agent, and therefore a therapeutic substance.

11. Regarding claim 18, Kaplan et al. further discloses a fitting (210 or 212) configured to accommodate a syringe on the hub for delivery of a therapeutic agent.

12. Kaplan et al. fails to disclose that when the elongated inner member is retracted, the flexible outer member folds and also fails to disclose a locking hub system.

13. However, Foster discloses that it is old and well known in the art to cause folding of a flexible outer member by retracting an elongated inner member (Fig. 17, 18, col. 9 lines 31-67). Foster further discloses that the inner member may be locked into position by a locking hub or other well-known means to prevent accidental folding of the outer member while it is withdrawn from the body. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Kaplan et al. to connect the distal ends of the inner and outer members and add a locking hub system such that when the inner member is retracted, the outer member folds adjacent an inner side of the stent as made obvious by Foster in order to gain the advantage of a convenient locking means to prevent accidental folding of the outer member during its withdrawal from the body.

14. Regarding claims 19-21, the details of the method steps are disclosed in the modified device of Kaplan et al. The device is placed proximate the target site and then

the inner member is retracted which folds the outer member adjacent an inner side of the stent and deploys the stent (Fig. 4D of Kaplan and col. 9 lines 31-67 of Foster).

15. Regarding claims 13, 14, 34, and 35, the size of both the cap and the outer member will determine how large the stent will be in its expanded configuration.

16. **Claims 3 and 4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al. in view of Chobotov et al. (U.S. 6,733,521). Kaplan et al. discloses the invention substantially as stated above, but fails to disclose that the diameter of the cap portion is greater than the diameter of the stent when the stent is disposed on the flexible outer member or that the cap portion has a bullet shape.

17. However, Chobotov et al. discloses that it is old and well known in the art to include a bullet shaped cap on a delivery system. Chobotov et al. discloses that cap (44) provides a streamlined bullet shape for easy passage within a patient lumen or vessel (col. 5 lines 52-56). Chobotov et al. further discloses a cap portion with a larger diameter than that of the stent before it has been expanded (Fig. 1). The larger diameter of the cap prevents the stent from slipping off the distal end of the device. Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention disclosed by Solano et al. to include a bullet shaped cap made obvious by Chobotov et al. in order to gain the advantage of easy passage within a patient lumen or vessel and to avoid accidental displacement of the stent in the distal direction.

18. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al. in view of Ryan et al. (U.S. 5,108,416). Kaplan et al. discloses the invention substantially as stated above but fails to disclose a cap that is made of silicone.

19. However, Ryan et al. discloses that it is old and well known in the art to include a cap which is made of silicone on a delivery device. Silicone is an ideal material because it is a resilient polymer. The end cap serves to prevent axial displacement of the stent as the delivery system and stent are guided through a patient. Therefore, it would have been obvious to one of ordinary skill in the art to add a silicone cap made obvious by Ryan et al. to the device disclosed by Kaplan et al. in order to gain the advantage of having a resilient cap that is not easily damaged and aids in navigation of the device through a human body.

20. **Claims 9 and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al. in view of Dubrul (U.S. 2002/0161392). Kaplan et al. discloses the invention substantially as stated above, but fails to disclose that the outer member comprises braided stainless steel wire or a plurality of wires.

21. However, Dubrul et al. discloses that it is old and well known in the art to use braided stainless steel wire or a plurality of wires for an outer member [0060] in a delivery device. These materials are well known in the art as strong materials that can form flexible, durable outer members that must move from expanded to contracted conditions. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Kaplan et al. to include an outer member made from a plurality of wires or of braided stainless steel wire made obvious by Dubrul et al. in order to gain the advantages of a strong, flexible, and durable outer member.

22. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al. in view of Vrba et al. (U.S. 6,623,504). Kaplan et al. discloses the invention

substantially as stated above but fails to disclose that the cap portion includes a radiopaque marker.

23. However, Vrba et al. discloses that it is old and well known in the art to include a radiopaque marker on the cap portion. Vrba et al. discloses that a radiopaque marker allows the physician to determine the position of the distal tip of the catheter within the body (col. 2 lines 47-68). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Kaplan et al. to include a radiopaque marker on the cap portion made obvious by Vrba et al. in order to gain the advantage of being able to determine the position of the distal end of the catheter within the body.

24. **Claim 25** is rejected under 35 U.S.C. 103(a) as being unpatentable over Solano et al. in view of Chobotov et al. (U.S. 6,733,521). Solano et al. discloses the invention substantially as stated above, but fails to disclose a cap that is bullet shaped.

25. However, Chobotov et al. discloses that it is old and well known in the art to include a bullet shaped cap on a delivery system. Chobotov et al. discloses that cap (44) provdes a streamlined bullet shape for easy passage within a patient lumen or vessel (col. 5 lines 52-56). Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention disclosed by Solano et al. to include a bullet shaped cap made obvious by Chobotov et al. in order to gain the advantage of easy passage within a patient lumen or vessel.

26. **Claim 27** is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Solano et al. in view of Foster (U.S. 6,500,182). Solano et al. discloses a first hub (56) attached to the proximal end of the

inner member and a second hub (30) attached to the proximal end of the outer member. The hubs can be locked together when gasket arrangement (40 and 44) is tightened. Solano et al. discloses that tan appropriate amount of tightening of the gasket arrangement allows for axial movement of the inner member while maintaining the sealing of the inflation lumen. It is reasonable to assume that further tightening would eventually lock the inner member in place and therefore, the hubs would be locked to each other. If the inner tube is locked when it is at its most distal position, the flexible outer member is fully extended.

27. Alternatively, Foster discloses that it is old and well known in the art to have a locking arrangement in order to prevent longitudinal movement of an inner member with respect to an outer member in order to avoid accidental deployment of expanding members, which could result in tissue damage (col. 9, lines 30-51). Therefore, if the locking mechanism disclosed by Solano et al. is not believed to be equipped to tighten to the point of preventing longitudinal movement of the inner member, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Solano et al. to have the gasket system prevent longitudinal movement of the inner member with respect to the outer member as made obvious by Foster in order to prevent accidental folding and expansion of the outer member.

28. **Claim 28** is rejected under 35 U.S.C. 103(a) as being unpatentable over Solano et al. in view of Ryan et al. Solano et al. discloses the invention substantially as stated above but fails to disclose a cap which is made of silicone.

29. However, Ryan et al. discloses that it is old and well known in the art to include a cap which is made of silicone on a delivery device. Silicone is an ideal material because it is a resilient polymer. The end cap serves to prevent axial displacement of the stent as the delivery system and stent are guided through a patient. Therefore, it would have been obvious to one of ordinary skill in the art to add a silicone cap made obvious by Ryan et al. to the device disclosed by Solano et al. in order to gain the advantage of having a resilient cap that is not easily damaged and aids in navigating through a human body.

30. **Claims 30 and 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Solano et al. in view of Dubrul (U.S. 2002/0161392). Solano et al. discloses the invention substantially as stated above, but fails to disclose that the outer member comprises braided stainless steel wire or a plurality of wires.

31. However, Dubrul et al. discloses that it is old and well known in the art to use braided stainless steel wire or a plurality of wires for an outer member [0060] in a delivery device. These materials are well known in the art as strong materials that can form flexible, durable outer members that must move from expanded to contracted conditions. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Solano et al. to include an outer member made from a plurality of wires or of braided stainless steel wire made obvious by Dubrul et al. in order to gain the advantages of a strong, flexible, and durable outer member.

32. **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over Solano et al. in view of Vrba et al. (U.S. 6,623,504). Solano et al. discloses the invention

substantially as stated above but fails to disclose that the cap portion includes a radiopaque marker.

33. However, Vrba et al. discloses that it is old and well known in the art to include a radiopaque marker on the cap portion. Vrba et al. discloses that a radiopaque marker allows the physician to determine the position of the distal tip of the catheter within the body (col. 2 lines 47-68). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Solano et al. to include a radiopaque marker on the cap portion made obvious by Vrba et al. in order to gain the advantage of being able to determine the position of the distal end of the catheter within the body.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KCS

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
4/15/06.